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Predictors of long-term outcomes after catheter-directed thrombolysis combined with stent implantation in acute deep vein thrombosis secondary to iliac vein compression

Feng Yu, MD[a], Shuai Wu, MD[a], Cong Chen, MD[a]

Abstract

The purpose of this study is to analyze predictive factors for long-term clinical outcomes after catheter-directed thrombolysis (CDT) combined with stent implantation for acute deep vein thrombosis (DVT) secondary to iliac vein compression (IVC). A retrospective analysis was performed to review clinical data and follow-up information on 52 patients who underwent CDT combined with stent implantation for acute DVT secondary to IVC from June 2015 to March 2020. Clinical outcomes including stent patency and incidence of postthrombotic syndrome (PTS) were investigated using Kaplan–Meier analysis. All included patients were categorized into 2 groups according to the presence of PTS. Potential risk factors, including age, gender, degree of iliac vein stenosis, time from onset to treatment, dosage of thrombolytic agent, stent extending below the inguinal ligament, and duration of anticoagulation for PTS were evaluated using multivariate logistic regression analysis. Over a median follow-up of 24 months, 4 individuals underwent reintervention due to in-stent stenosis or stent compression. Primary stent patency was 98.1% at 1 month, 94.2% at 6 months, 90.4% at 12 months, and 88.5% at 24 months. Freedom from PTS was 98.1% at 6 months, 84.6% at 12 months, and 75% at 24 months. No treatment-related mortality or morbidity was observed. Based on the development of PTS, 13 patients with PTS were classified into group A and 39 patients without PTS were regarded as group B. Upon multivariate logistic regression analysis, key prognostic factors for PTS were degree of iliac vein stenosis and time from onset to treatment. CDT combined with stent implantation is safe and effective for acute DVT secondary to IVC in the long-term perspective. Severe iliac vein stenosis and longer period from onset to treatment may be associated with a higher risk of PTS.

Abbreviations: CDT = catheter-directed thrombolysis, DVT = deep vein thrombosis, IVC = iliac vein compression, PTS = postthrombotic syndrome

Keywords: Deep vein thrombosis, Iliac vein compression, postthrombotic syndrome, prognosis, thrombolysis

1. Introduction

Iliac vein compression (IVC) is the most common cause of iliofemoral deep venous thrombosis (DVT).[1] It is estimated that 18 to 49% of left-sided DVT is associated with IVC.[2–4] IVC is characterized by compression of the left common iliac vein against the fifth lumbar vertebra by the right iliac artery, and has a prevalence of 25% in the general population.[5,6] Such compression leads to collagen scarring that contributes to occlusion of the iliac vein. Long-term outcomes of this condition are poor, with only conservative management of anticoagulation therapy and compression stockings available.[7–9] More aggressive modalities of catheter-directed thrombolysis (CDT) and endovenous stenting have become the optimal option of care in the management of DVT caused by IVC.[10] Several studies have demonstrated the safety and effectiveness of CDT and stenting in treating acute DVT secondary to IVC,[10,11] however, no previous studies have focused on the risk of postthrombotic syndrome (PTS) in these patients from longer monitoring periods. PTS is the most common complication of DVT, which develops in 20 to 50% of patients within 2 years after initial diagnosis, having an important socioeconomic impact.[12,13] Since therapeutic options for PTS are very limited, it is important to identify factors that contribute to PTS in patients who undergo CDT combined with stenting and mitigate them accordingly.

From this perspective, data of patients with DVT secondary to IVC was analyzed to assess independent predictors for PTS after CDT combined with stenting. The secondary objective was to investigate cumulative rates of venous patency over time.

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The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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2. Materials and methods

2.1. Study design and participants

A retrospective analysis of electronic medical record data of DVT patients with CDT and iliofemoral venous stents placed from June 2015 to March 2020 was performed. The study adhered to the tenets of the Declaration of Helsinki and was approved by the institutional review board of Jiangyin Hospital of Traditional Chinese Medicine. Informed consent was collected from each patient during follow-up.

Inclusion criteria were as follow: age ≥ 18 years; initially diagnosed with left-side acute iliofemoral DVT (within 14 days after onset of symptom) and IVC (degree of stenosis > 50% confirmed by intravascular ultrasonography); underwent CDT in combination with iliac vein stent implantation. Exclusion criteria included a history of venous thromboembolism; right-sided or distal left-side DVT; high risk of bleeding or contraindication to anticoagulation and thrombolysis.

2.2. Procedural details

All interventional procedures were performed under local anesthesia. Ipsilateral percutaneous femoral or popliteal access was established under the guidance of ultrasound. A temporal inferior vena cava filter was placed for embolic protection prior to CDT and stenting. The procedure of CDT and iliac vein stenting were performed as previously described.[14] In essence, A Uni-Fuse thrombolytic catheter was inserted into the affected vein and advanced through to cover the thrombotic segment. Urokinase was delivered at a bolus dose of 200,000 to 600,000 U/day, pumped through a multiple side-holes catheter. Subcutaneous low-molecular weight heparin was given simultaneously at 4000 U/12 hours with a target of 1.2- to 1.7-fold level of activated partial thromboplastin in comparison to reference values (target 40–60 seconds). Clot burden during thrombolysis was monitored daily by venography.

Infusion of thrombolytic agents were discontinued if residual thrombi were <10% as detected by venography. After thrombolysis, balloon angioplasty and iliac vein stenting was followed by intravascular ultrasonography interrogation and a bilateral anteroposterior venogram to confirm the exact location, degree, and length of stenotic lesion. SMART control (Cordis) or Wallstent (Boston Scientific) was implanted at the discretion of the physician. postdilation was carried out using a 16- or 18-mm balloon angioplasty. This was followed by venography to guarantee adequate coverage and inflation of the stenotic

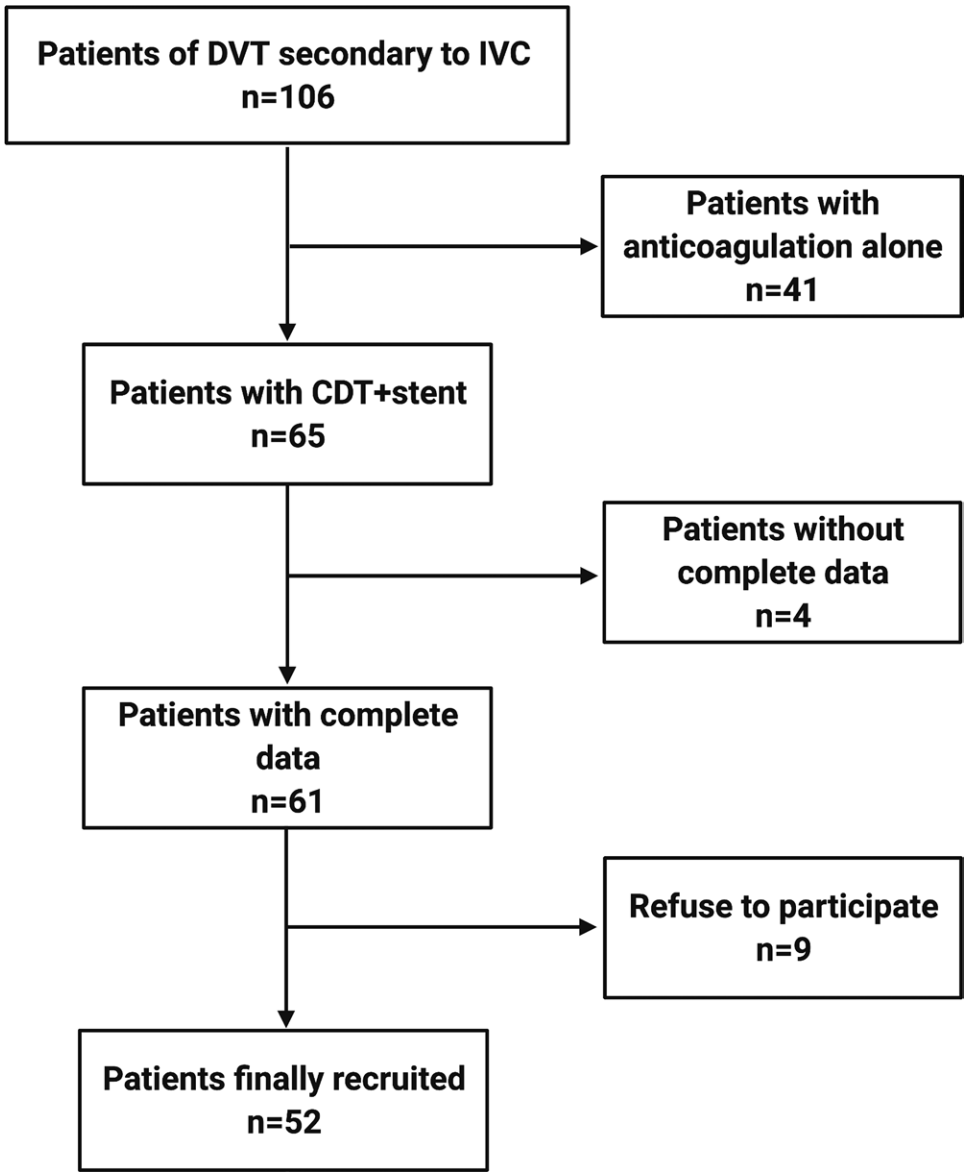

Figure 1. Flow chart of included patients.

lesion. After intervention, patients received anticoagulation with rivaroxaban for at least 3 months.

2.3. Outcomes assessment and follow-up

Details of the interventional procedure were recorded, and any procedure-related complication was identified. An effective case was defined as >70% patency for stenting. Initial patency was defined as inline flow through the implanted stent segment into the inferior vena cava, without contrast stasis, and emptying delay determined by postoperative venography. Clinical follow-ups were scheduled at 1, 2, 6, 12 months, and every year after discharge using duplex ultrasound. Primary patency was defined as primary treatment success without either DVT recurrent in the affected limb or reintervention for a certain period. Presence of PTS was evaluated according to a Villalta score of ≥ 5 points.

2.4. Statistical analysis

Characteristics of the patients were summarized using tabulations for categoric factors and means plus or minus standard deviations for continuous variables. Continuous variables were compared using Mann–Whitney *U* or Kruskal–Wallis tests. Categorical data were compared by using a Chi-square test or Fisher exact test. Primary patency and prevalence of PTS were performed using a Kaplan–Meier curve. Potential risk factors for PTS were identified using multivariate logistic regression. A *P*-value < 0.05 was considered to indicate a statistically significant difference.

Table 1

Baseline characteristics of patients.

Variables	Value
Median age, yr	51
Male, n	21
Average time from onset to treatment, days	4.36
Degree of stenosis, n	
Mild (50–59%)	25
Moderate (60–89%)	22
Severe (> 90%)	5

3. Results

3.1. Patients' characteristics

A total of 52 patients meeting the inclusion criteria were recruited in the present study. The flow chart of the study is shown in Fig. 1. The median age was 51 years old. There was a preponderance of women (31:21). The average time from onset to treatment was 4.36 days. Twenty-five patients showed mild stenosis (degree of stenosis 50–59%), 22 had moderate stenosis (60–89%), and 5 had severe stenosis (>90%) at diagnosis. Table 1 shows characteristics of the patients.

3.2. Clinical outcomes

Forty patients received 1 stent and 12 patients received distal extension with a second or third stent. All patients presented with leg edema or pain before treatment. The mean number of stents placed per patient was 1.25 and average diameter of the proximal stent was 16.15 mm. The mean thrombolytic procedure time was 25.13 hours and mean urokinase dose was 280 million U. Complete thrombolysis success was achieved in 41 patients; 11 patients had > 70% of thrombus removed. The initial patency rates were 100% (Fig. 2). All patients experienced relief of symptoms including improved pain and reduced edema. Procedure-related complications were observed in 3 patients including 2 minor bleeding and 1 hematemesis. Median follow-up time was 24 months. Primary patency was 98.1% at 1 month, 94.2% at 6 months, 90.4% at 12 months, and 88.5% at 24 months (Fig. 3). Four patients that had symptomatic in-stent stenosis or stent compression underwent reintervention. Of these patients, 3 patients received an additional stent and the other one underwent balloon angioplasty alone. The symptom of in-stent restenosis or stent compression include pain, swelling, and slow-healing ulceration. In addition, the venograms identified more than 50% restenosis in all of the 4 patients before reintervention. Another 2 patients encountered recurrence of DVT and underwent thrombolysis therapy. Prevalence of PTS is shown in Fig. 4 and Villalta scores of the study population are presented in Fig. 5. According to the presence of PTS, all included patients were categorized into 2 groups. Thirteen patients who developed PTS during follow-up were classified into group A and the remaining 39 patients were in group B.

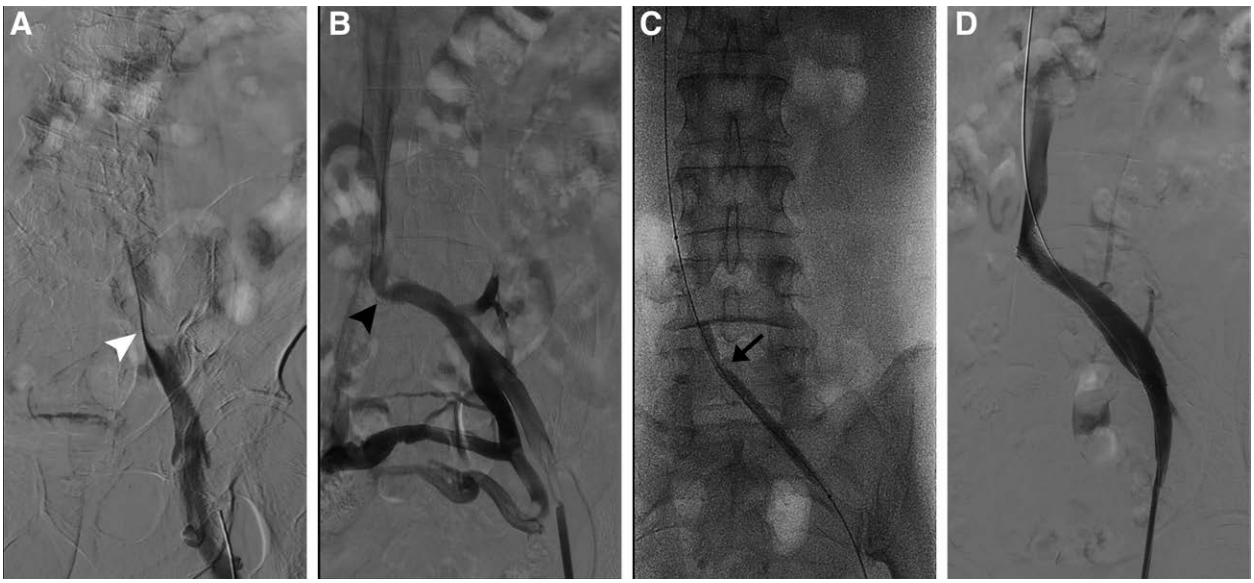

Figure 2. Representative DSA images for treatment procedure. (A) Venogram of left iliac indicated thrombus in the iliac vein (white arrowhead), (B) venography showed stenotic lesion in the left iliac vein (black arrowhead), (C) angioplasty with balloon dilatation in the stenotic segment (arrow), (D) venography showed good patency of the iliac vein after stenting.

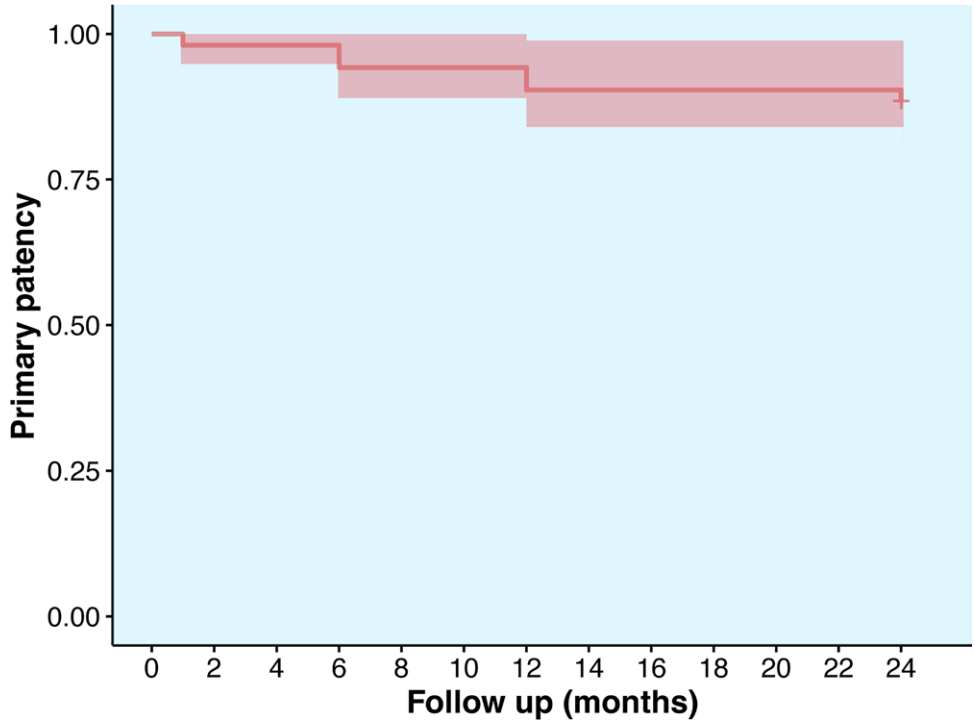

Figure 3. Primary patency during follow-up.

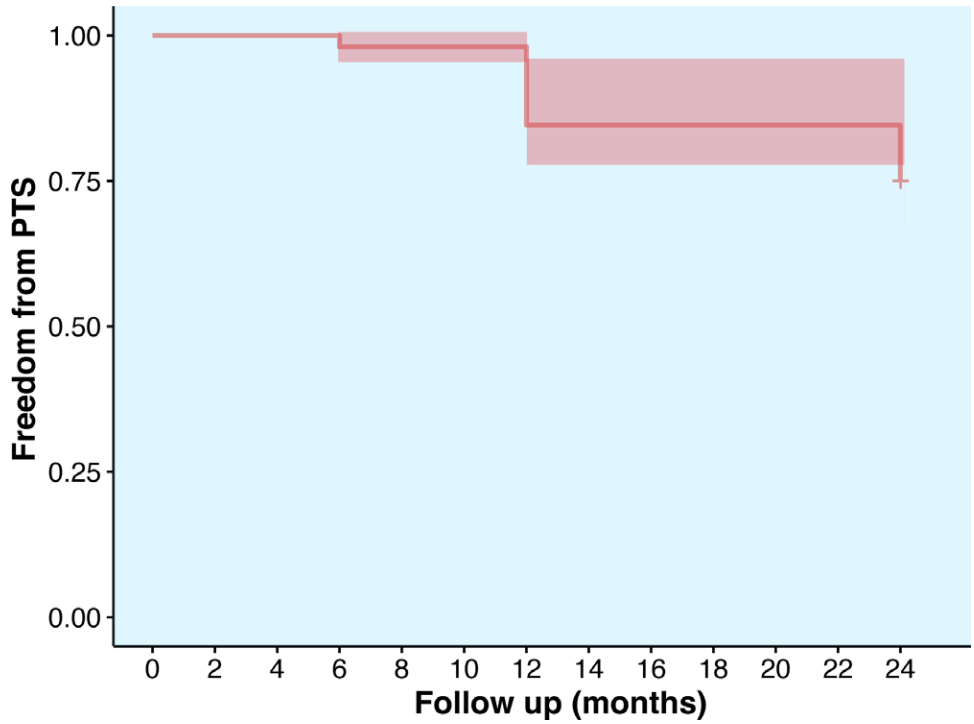

Figure 4. Freedom from PTS during follow-up. PTS = postthrombotic syndrome.

Villalta score was significantly higher in patients of group A when compared to group B.

3.3. Predictors of PTS

Seven potential candidate predictors, including age, gender, degree of iliac vein stenosis, time from onset to treatment, dosage of thrombolytic agent, stent extending below the inguinal ligament, and duration of anticoagulation were selected for predicting the development of PTS in patients who received CDT combined with iliac vein stenting. In univariate analysis, degree of iliac vein stenosis, time from onset to treatment, and duration of anticoagulation were identified to be significantly different between the 2 groups (Table 2). However, multivariate logistic analysis confirmed only degree of iliac vein stenosis and time from onset to treatment were associated with presence of PTS (Fig. 6).

4. Discussion

Pulmonary embolism (PE) is a life-threatening comorbidity during acute phase in DVT patients. According to a previous study, the incidence of PE is around 7% in patients with combined lower extremity deep venous thrombosis and iliac vein stenosis.[15] In the present study, it is demonstrated that CDT combined with iliac vein stenting is effective and safe for acute DVT secondary to IVC. No symptomatic PE was observed during hospital stay or after discharge. Although anticoagulation is still the first-line treatment for most patients with confirmed VTE,[16,17] thrombolysis is much more effective in thrombus resolution and preservation of venous function, especially for proximal DVT. CDT, as a method to quickly remove the thrombus, has become a more reliable and effective approach for treating acute DVT than anticoagulation alone.[18] Besides, the mean dosage of thrombolytic agent was 280 million unit in this study. It has been proven that patients received less thrombolytic drug with CDT when compared with that of peripheral thrombolysis.[19] Reduced thrombolytic dosage is associated with less bleeding complication as well. These results show that only 2 patients encountered minor bleeding and one suffered from hematemesis. These 3 patients recovered after thrombolysis was discontinued. Apart from local thrombolysis, an inferior vena cava filter was used for all patients for prevention of PE during thrombolysis. Currently, the Society of Interventional Radiology, the American Heart Association, and British Committee for Standards in Hematology all recommend filter placement in patients who have failed or have an absolute contraindication to pharmacological anticoagulation.[20–22]

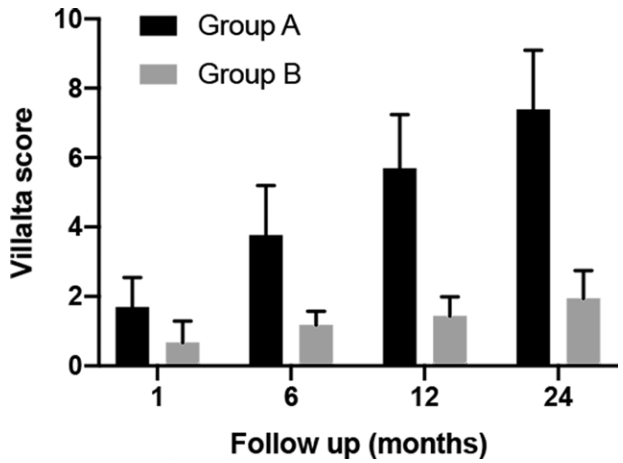

Figure 5. Villalta score during follow-up.

However, there is still controversy on indication for inferior vena cava filtering and different guidelines have differing recommendations on the absolute, relative, and prophylactic indications. In this study, a more aggressive strategy of placing retrieval filters for all patients was employed. The results show that all filters were removed after completion of thrombolysis and no filter-related complications occurred.

This data also indicates that restoration of stenotic lesion in iliac vein is of importance in lowering the risk for recurrence of DVT. In this study, the incidence of recurrent DVT was 3.8%, which is comparatively lower than that in previous studies. Funatsu et al[23] reported that recurrence of DVT was documented in 8% of May–Thurner syndrome patients after iliac vein stent implantation. Results from another retrospective study showed that the rate of recurrent thrombotic occlusion was 7.8% after CDT in combination of iliac vein stenting.[24] These discrepancies may be due to the restoration of stenosis. All patients achieved complete restoration with CDT and stenting in this study while the other studies report incomplete restoration after endovascular management of intractable chronic thrombus.[24]

PTS is the most common long-term complication of DVT. The main goals of treatment have been to minimize venous congestion symptoms, incidence, and severity of PTS. Results of the CaVenT trial demonstrated an 11.5% reduction of incidence of PTS in patients who underwent CDT compared with those who received anticoagulation alone.[7] More high-quality evidence from the ATTRACT trial includes moderate-to-severe PTS occurred less often with CDT when compared with anticoagulation alone.[25] In addition, while there are no randomized, controlled prospective trials exploring the development of PTS in DVT patients who underwent CDT combined with iliac vein stenting, this data suggests these therapeutic approaches are beneficial for the prevention of PTS from a long term perspective. A total of 13 (25%) patients developed PTS during follow-up, most of which were mild (Villalta score 5–9 points). Data derived from the ATTRACT trial indicated the incidence of PTS was 48.2% in DVT patients who underwent pharmacochemical CDT.[26] Yet other research reports a much lower incidence (2.1%) of PTS in patients who underwent pharmacochemical CDT plus stenting.[27] However, the study did not show baseline of stenotic lesion and other details of patient characteristics, which might influence the development of PTS.

Based on data from previous studies,[28,29] we further explored the predictive factors associated with PTS after CDT combined with stent implantation for acute DVT secondary to IVC. To the best of our knowledge, this is the first study to investigate prognostic factors for PTS in iliofemoral DVT secondary to IVC in patients who underwent CDT with stent implantation. This data indicates that degree of iliac vein stenosis and time from onset to treatment are associated with

Table 2

Univariate analysis for the prediction of PTS occurrence.

	Group A	Group B	*P* value
Age, yr	53.76	50	.228
Gender distribution, n			.870
Male	5	16	
Female	8	23	
Degree of stenosis, n			.006
Mild	3	22	
Moderate	6	16	
Severe	4	1	
Time from onset to treatment, days	5.6	3.9	.032
Dosage of thrombolytic agent, million unit	278.5	280.5	.908
Stent extending below the inguinal ligament	4	8	.447
Anticoagulation duration, days	6.6	11.1	.047

PTS = postthrombotic syndrome.

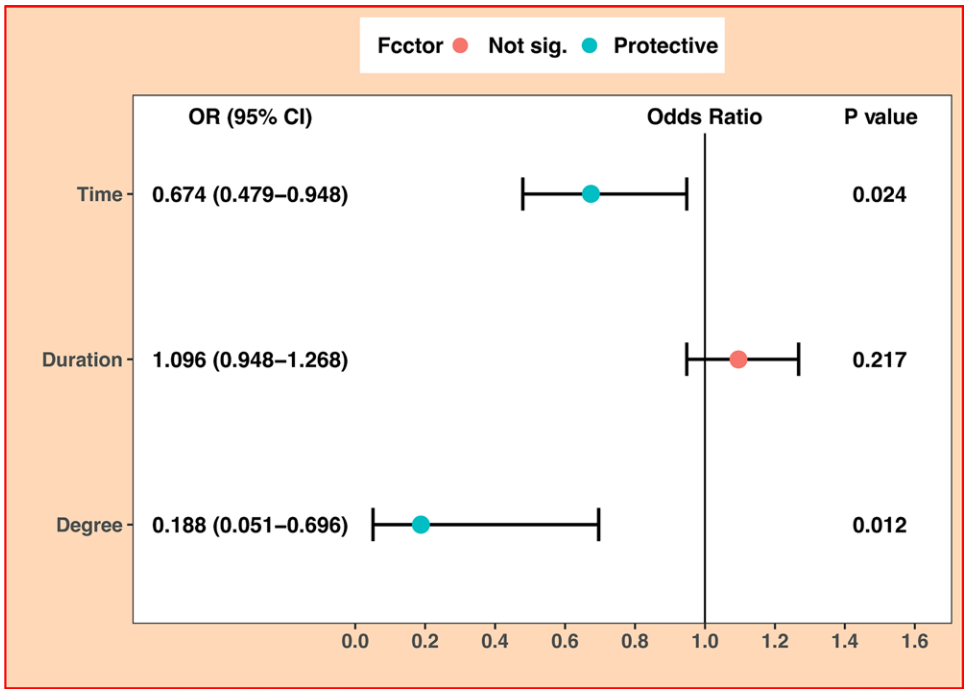

Figure 6. Forest plots of the risk factors for PTS. Time indicates time from onset to treatment; Duration indicates duration of anticoagulation; Degree indicates degree of iliac vein stenosis. PTS = postthrombotic syndrome.

presence of PTS. Iliac vein stenosis is related to peripheral venous hypertension, which contributes to the development of PTS. Previous studies report that clinical features of iliac vein stenosis are related to peripheral venous hypertension and patients with severe initial iliac vein stenosis experience higher recurrence of symptoms.[30,31] From the perspective of pathology, more sever vein stenosis brings less blood flow and higher venous pressure, reducing calf muscle perfusion and increasing tissue permeability.[32] However, Aurshina et al[33] describe no significant correlation between venous symptom and degree of iliac vein stenosis. This discrepancy may be due to different inclusion criteria and the imaging modality used for evaluation of stenosis degree. In that study, patients who had undergone magnetic resonance imaging of the pelvis for various indications were recruited. Besides, another study has drawn a different conclusion; iliac vein stenosis as measured by magnetic resonance imaging correlates significantly with lower limb symptom severity.[34] Time from onset to treatment is also an independent factor in predicting the development of PTS. A longer period of venous obstruction results in pathological dilatation of the capillaries with increased endothelial permeability for plasma proteins and erythrocytes in the skin and subcutaneous tissues resulting in edema, pigmentation, fibrosis, and ulceration. Spáčil et al[35] have demonstrated that delayed onset of treatment increases risk of residual thrombosis in the affected veins for DVT patients. This can be explained by the results from another study in which the authors identified that longer symptom durations lead to worse lysis grade with CDT in DVT patients.[36] There is little doubt that incomplete thrombolysis contributes to the onset of PTS.

4. Conclusion

In conclusion, these data confirm that CDT combined with stent implantation is safe and effective for acute DVT secondary to IVC in the long-term perspective. Severe iliac vein stenosis and longer period from onset to treatment might be associated with a higher risk of PTS. The limitations of the current study are retrospective design and its relatively small sample size. Thus, more interventional techniques including ultrasound-assisted thrombolysis should be evaluated in future studies.

Author contributions

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Formal analysis: Feng Yu, Cong Chen.
Methodology: Feng Yu, Shuai Wu.
Resources: Shuai Wu.
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Supervision: Shuai Wu.
Writing—original draft: Feng Yu.
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